DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

April 12, 2001

Jackie Hernandez
Off-Site Supervisor
Maricopa Medical Center
2601 East Roosevelt
[mailing address at: P.O. Box #5099]
Phoenix, AZ 85008

W/L Number: 37 - 01
Inspection ID: 1220280006
CFN: 20-29,592
FEI: 1000518846

Dear Ms Hernandez:

We are writing to you because on March 29, 2001, your facility was inspected by a representative of the State of Arizona acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

- Level 1: Processor quality control (QC) records in the month of June 2000 were missing for at least 30% of those operating days for processor #1 (a [redacted] machine, model [redacted] or [redacted]) located in room #1.

- Level 1: Processor QC records were missing at least 5 consecutive days for processor #1 (a [redacted] machine, model [redacted] or [redacted]) located in room #1.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

re: Maricopa Medical Center
re: W/L Number 37 - 01

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. This Level 2 finding is:

- Level 2: Phantom QC records were missing for at least two weeks but less than four weeks for unit #3 (a [redacted] machine, serial number [redacted]) located in room #1.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations; and

- please provide sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

re: Maricopa Medical Center
re: W/L Number 37 - 01

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas (MQSA Auditor) at telephone number (949) 798-7708.

Sincerely,

Alonza E. Cruse
District Director

cc:

Ms Priscilla F. Butler
Director, Breast Imaging Accreditation Programs
Standards & Accreditation Dept.
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